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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/828, 143	03/24/97	HSIA	H 24400-101

<input type="checkbox"/>	HM12/0820	<input type="checkbox"/> EXAMINER
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		<input type="checkbox"/> ART UNIT
		<input type="checkbox"/> PAPER NUMBER
		1651
		<input type="checkbox"/> DATE MAILED:
		08/20/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/828,143	Applicant(s) Hsia
	Examiner Irene Marx	Group Art Unit 1651

Responsive to communication(s) filed on Aug 6, 1999.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 16-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 16-24 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Since this application is eligible as a Continued Prosecution Application under 37 CFR 1.153(d), the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.153(b). Applicant's amendment filed on 8/6/99 has been entered.

Claims 16-24 are being considered on the merits. Claims 9-11 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is confusing, vague and indefinite in that the weight percent is not specified as being wet or dry weight.

Claim 18 is confusing in that the term "bacteria" is plural. Thus, "bacteria is" is grammatically incorrect. In addition, the correct names of the genera of bacteria are: *Lactobacillus*, *Streptococcus*, and *Pediococcus*. Correction is required. In addition, the use of the term "strains" appears redundant and should be deleted.

The presence of *Streptococcus* in the nutritional composition is queried, inasmuch as most strains in this genus are pathogenic. If specific species are intended, the claims should be amended accordingly.

Claim 20 is confusing in the recitation of "whey, animal and soy protein isolates", since it is unclear whether "protein isolates" is intended to modify "whey,

animal and soy" or just "soy". Also it is unclear what is intended by "protein isolates" in this context regarding "whey" and, particularly, "animal". If "concentrates" are intended, the claim should be amended accordingly.

Claim 23 is confusing and improper in that it depends on itself. Claim 24, dependent on 23, is confusing in that it is contradictory and inconsistent with claim 23.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynn taken with Gelinas, and Spiller *et al.* and further taken with Prescott *et al.*, Jolly, Friend and El-Megeed *et al.* for the reasons as stated in the last Office action and the further reasons below.

All of the above references except Prescott *et al.* have been discussed previously.

Prescott *et al.* adequately demonstrate the that the benefits of brewer's yeast and baker's yeast as sources of nutrients such as proteins and vitamins are well known in the art (See, e.g., pages 558-559). Clearly, one of ordinary skill in the art would have compelling motivation to add yeast, particularly baker's or brewer's yeast to a protein and *Lactobacillus* containing composition. Moreover, yeast extract is recognized in the microbiological arts as a suitable source of protein and growth factors for bacteriological media.

Applicants' arguments have been fully considered but they are not deemed to be persuasive.

Applicants appear to argue that the amount of yeast added is not the same as is present in the instant composition. However, during the proofing or rising period of the dough during bread making the yeast cells multiply and produce CO₂. Consequently, one of ordinary skill in the art would have a reasonable expectation that

there would be a greater number of cells in the rising bread dough than in the original preparation. Moreover, as noted *supra* Prescott *et al.* disclose the benefits of supplementation with brewer's yeast and baker's yeast because of their value as abundant sources of nutrients such as vitamins and protein (See, e.g., pages 558-559). One of ordinary skill in the art would have compelling motivation to add yeast, particularly baker's or brewer's yeast to a protein and *Lactobacillus* containing composition. As noted, yeast extracts are well known additives of nutritional formulas and of culture media.

As to the arguments that the yeast material is intended to provide nutrients for the *Lactobacillus*, applicants have not indicated when the nutrients are to intended be used by the solid, dried, viable *Lactobacillus*. During dormancy in the dried preparation, the "vitality" of the *Lactobacillus* is maintained without feeding. It does not appear likely that the yeast would be useable as a nutrient during the dormancy period, particularly in the absence of evidence thereof. After reconstitution in the gut of an animal, it cannot be readily ascertained whether or not the presence of 1% more of non-living yeast would significantly affect the "vitality" of *Lactobacillus*.

The stable preparation shown in the specification at page 12, Example 1, contains a large amount of soy protein, and the amount of yeast is greater than the amount of *L. acidophilus*. There is no clear correlation between the invention as claimed and this preparation touted as having advantageous properties regarding storage stability of bacteria. Moreover, it is not clear that this material is in dry, granular form. The effects of varying the proportions of ingredients in the manner claimed cannot be readily ascertained.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA

1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

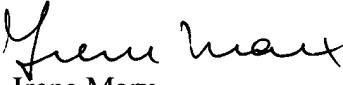
Applicants have not demonstrated any unexpected properties of the composition as claimed.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Irene Marx
Primary Examiner
Art Unit 1651